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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|-------------------------------|
| 10/018,623 | 03/22/2002 | Eberhard Fritz | 3993.003 | 4998 |
| 7590 | 12/02/2004 | | | EXAMINER GILBERT, SAMUEL G |
| Stephan A Pendorf Pendorf & Cutliff PO Box 20445 Tampa, FL 33622-0445 | | | ART UNIT 3736 | PAPER NUMBER |

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/018,623 | FRITZ ET AL. | |
| Examiner | Art Unit | | |
| Samuel G Gilbert | 3736 | | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 16 August 2004.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 23-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 28-30,41 and 47 is/are allowed.
- 6) Claim(s) 23-27,31-40,42-46 and 48-52 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All
 - b) Some *
 - c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8/16/2004</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Information Disclosure Statement

The information disclosure statement filed 8/16/2004 has been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 23, 24, 25, 31, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Tokita et al (4584991).

Tokita teaches treating elements –28- the treating elements are strung on wire like member –32- and plastic coating –34- retains the spacing and elements -30- provides means for containment. Further the seeds are placed in flexible elongate container –36-. The flexible tube provides a deflection site as shown in figure 1 where the tube bends. Since the tube bends over the entire length of the seeds there is inherently a deflection site between the seeds. Applicants attention is invited to figure1 and column 4 lines 42-62.

Claim 24 – tube –36- is a hollow cylinder.

Claim 25 – tube –36- is flexible see column 4 line 61.

Claim 31 – the beads as set forth by definition would have rounded ends.

Claim 32 – the wire like member –32- is a spacer.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 36 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tokita et al. (4584991).

Claims 36 and 37 – the exact radiation source used by Tokita is not set forth.

The applicant has not set forth any criticality in the exact source to be used. It is generally accepted in the medical arts that the radiation source is generally selected based on the therapy to be preformed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use any of the claimed sources as known radiation sources.

Claims 23-27, 31, 34-40, 42-46, and 48-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (5,863,284) in view of Good (5,342,283).

Claim 23 - Klein teaches a radiation source, as shown in figures 36-37A, including at least two treating elements -206- in an elongated container -198-. The container includes deflection sites -199- in figures 36A and 37A and any point along the

continuous bend in figures 36 and 37. The use of containment means for the radiation sources are not set forth. The radiation sources are only described as generally spherical radionuclides. Good teaches spherical sources including layers -18- and -20- to confine the radiation emitting layer to protect, seal, identify or filter the radiation as taught in column 40 lines 48-66. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the radiation elements of good for the spheres taught by Klein in order to provide a protective containment layer/layers as taught by Good to protect, seal, identify or filter the radiation.

Claims 24 and 25 - container -198- is a hollow container of highly flexible material.

Claim 26 - the container can be an alloy of nickel-titanium, column 21 lines 27-30.

Claim 27 - the exact titanium alloy used for the container is generally an obvious matter of design choice to practitioners in the medical arts. The selection of a particular alloy of the container in the absence of showing any criticality the selection of any particular titanium alloy out of all titanium alloys is of no patentable significance. In the absence of showing any criticality the selection of any particular titanium alloy would be a matter of ordinary engineering design choice.

Claim 31 - each side of the spherical treating elements are going to be rounded.

Claim 34 - Klein teaches a radiation source, as shown in figures 36-37A, including at least two treating elements -206- in an elongated container -198-. The container includes deflection sites -199- in figures 36A and 37A and any point along the

continuous bend in figures 36 and 37. The use of containment means for the radiation sources are not set forth. The radiation sources are only described as generally spherical radionuclides. Good teaches spherical sources including layers -18- and -20- to confine the radiation emitting layer to protect, seal, identify or filter the radiation as taught in column 40 lines 48-66. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the radiation elements of good for the spheres taught by Klein in order to provide a protective containment layer/layers as taught by Good to protect, seal, identify or filter the radiation. The claim includes the following, "wherein the at least two treating elements are spaced from each other and fixed to the inner wall of the container". It is well settled in the medical arts that "fixed" is a word of relative meaning; it can have many shades of meaning, from absolutely unchangeable to relatively unchangeable. Palmer v. McLamore, Minneman & Dunn (CCPA) 105 USPQ 33. It is the examiner's position that because the elements -206- of Klein fill the length of the container -198- the positioning of the elements with respect to the inner wall of the container is relatively unchangeable and therefore fixed to the inner wall of the container.

Claim 35 - Good teaches metallic containment means, column 40, line 67 through column 41, line 10.

Claims 36 and 37 - Sr-90 and Y-90 are both taught in Klein, column 21, lines 20-23.

Claim 38 - the examiner is taking element -100- as a catheter and a first lumen -108-. Further a radiation source as shown in figures 36-37A, including at least two

treating elements -206- in an elongated container -198-. The container includes deflection sites -199- in figures 36A and 37A and any point along the continuous bend in figures 36 and 37. The use of containment means for the radiation sources are not set forth. The radiation sources are only described as generally spherical radionuclides. Good teaches spherical sources including layers -18- and -20- to confine the radiation emitting layer to protect, seal, identify or filter the radiation as taught in column 40 lines 48-66. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the radiation elements of good for the spheres taught by Klein in order to provide a protective containment layer/layers as taught by Good to protect, seal, identify or filter the radiation.

Claim 39 - Sr-90 and Y-90 are both taught in Klein, column 21, lines 20-23 and container -198- is a hollow container of highly flexible material.

Claim 40 Klein teaches containment vessel -214-.

Claim 42 - a fluoroscopic device is used, see column 5 line 60 through column 6 line 5. End caps -204- can provide a fluoroscopy device.

Claims 49 and 51 - guidewire -114-.

Claims 50 and 52 - lumen -172- provides a second lumen.

Claims 43-46 and 48 - applicant's attention is invited to the embodiment of Figure 20A. The radiation source is pushed and pulled by element -114-.

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Claims 32 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klein (5,863,284) in view of Good (5,342,283) as applied to claim 23 above, and further in view of Cutrer (5,997,463). The combination of Klein (5,863,284) in view of Good (5,342,283) teaches an apparatus as claimed but does not separate the treating elements with spacers. Cutrer teaches the use of spherical markers -1014- separating treatment elements -1012- elements. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the markers of Cutrer in the container of Klein between the treatment elements to gain the advantage of providing imaging markers as taught by Cutrer. Further, it is old and well known in the medical arts to use spacers as needed in a radiation source to obtain the desired radiation pattern.

Allowable Subject Matter

Claims 28-30, 41 and 47 are allowed.

Response to Arguments

Applicant's arguments filed 8/16/2004 have been fully considered but they are not persuasive. The applicant argues that Tokita does not teach or suggest a radiation source for endovascular treatment. The only language present in the rejected claims directed to endovascular use is in the form of intended use statements, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed

invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). It is the examiners position that radiation source -28- is capable of being used in the cardiovascular system inside a catheter system possibly in a guidewire lumen. The source -28- is sufficiently flexible to be passed through such a catheter.

The applicant argues that the carriers -12- and -14- would not be suitable for endovascular radiation treatment. It is the examiner's position that only portion of Tokita et al required to meet the claim language is element -28- which is clearly capable of being used in an endovascular system.

On page 12, the applicant argues that Tokita does not teach an element that is equivalent to the elongated container and points to element -34- as being a mere coating. It is the examiner's position as previously pointed out that element -36- is a container while element -34- was a means for containment. Element -34- clearly contains the radioactive sleeves -30-.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US Patent 6506145 teaches a related delivery device which could be used in place of Klein. Applicant's attention is invited to figure 4 and 5B.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel G Gilbert whose telephone number is 703-308-3553. The examiner can normally be reached on M-F 5:30-2:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 703-308-3130. The fax phone number for the organization where this application or proceeding is assigned is 703-308-0758.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Samuel G Gilbert
Primary Examiner
Art Unit 3736

sgg